

Massachusetts. The FTC then settled that action with Barefoot and Trudeau, agreeing to final judgments with both defendants.⁷ This final judgment resolved all claims against the two main protagonists of the coral calcium infomercial, and includes their liability for the coral calcium infomercial that is the subject of the present action.⁸ Thus, the only remaining issue is whether Barefoot or Trudeau is in “privity” with the DMC Defendants.⁹

“It has long been recognized that the federal doctrine of ‘non-mutual claim preclusion’ permits a non-party defendant in a prior action to raise a defense of *res judicata* in a subsequent suit.” *Andrews-Clarke v. Lucent Techs., Inc.*, 157 F.Supp.2d 93, 100 (D. Mass. 2001). The only question is whether there is a sufficiently “close and significant” relationship between the later named defendant and the original defendants. *Id.* (citing *In re El San Juan Hotel Corp.*, 841 F.2d 6, 10 (1st Cir. 1988)). This determination is necessarily an issue of fact, as courts “are no longer bound by rigid definitions of parties or their privies for purposes of applying ... *res judicata*.” *United States v. ITT Rayonier, Inc.*, 627 F.2d 996, 1003 (9th Cir. 1980). Rather, courts “base the determination of whether a sufficiently close relationship exists for purposes of *res judicata* on a functional analysis and on the reasons for holding a party bound by a prior judgment, and not on labels and rigid rules.” *Davis, Wright & Jones v. National Union Fire Ins. Co.*, 709 F. Supp. 196, 201-02 (W.D. Wash. 1989), *aff’d*, 897 F.2d 1021 (9th Cir. 1990) (citing *Gambocz v. Yelencsics*, 468 F.2d 837 (3d Cir. 1972). “Because of the fact intensive nature of the these

⁷ Despite the fact that Trudeau and Barefoot collectively sold over \$120 million of coral calcium through infomercial advertising, Barefoot settled for no payment at all, and Trudeau settled for \$2 million.

⁸ *Res judicata* bars “all rights of the plaintiff to remedies against the defendant with respect to all or any part of the transaction, or series of connected transactions, out of which the action arose.” Restatement (Second) of Judgments § 24(1) (1982). The First Circuit has adopted a transactional approach to determine whether causes of action are similarly related, boiled down to “whether the causes of action arise out of a common nucleus of operative facts.” *Massachusetts School of Law*, 142 F.3d at 38. See *Aunyx Corp.*, 978 F.2d at 6-7 (discussing First Circuit’s transactional approach to preclusion).

⁹ Because of the fact intensive nature of the *res judicata* inquiry, the DMC Defendants have not themselves moved for summary judgment at this time on the issue, but intend to address the issue at trial.

inquiries, there is no clear test that can be employed.” *Tyus v. Schoemehl*, 93 F.3d 449, 454 (8th Cir. 1996). *See also Harrison v. Bloomfield Bldg. Indus., Inc.*, 435 F.2d 1192, 1195 (6th Cir. 1970) (the existence of privity in a given case is considered to be a question of fact); *Vets North, Inc. v. Libutti*, 2003 WL 21542554, at *11 (E.D.N.Y. Apr. 21, 2003) (“Contemporary courts have broadly construed the concept of privity, far beyond its literal and historic meaning, to include any situation in which the relationship between the parties is sufficiently close to supply preclusion”) (internal citations and quotations omitted).

Among other facts considered by courts in addressing the privity required to establish *res judicata* is the conclusion that two parties were “co-conspirators” or in a conspiratorial relationship in connection with the challenged conduct. *See In re El San Juan*, 841 F.2d at 11 (new defendant can raise *res judicata* where new defendant and original defendant were alleged to be “co-perpetrators”); *Burns v. Town of Laoine*, 2000 WL 1612704, at *3 (D. Me. Sept. 21, 2000) (where plaintiff alleged that parties were co-conspirators, claim preclusion applied). In *Betances v. Quiros*, 603 F. Supp. 201 (D.P.R. 1985), for example, the plaintiff alleged that Price Waterhouse had assisted certain government officials in defrauding him. Although Price Waterhouse’s activities were limited to producing an allegedly false audit report, the court dismissed the firm under principles of *res judicata*, determining that there was a sufficiently close relationship to conclude that privity existed. *See also Amadasu v. Bronx Lebanon Hosp. Center*, 2005 WL 121746, at *8 (S.D.N.Y. Jan. 21, 2005) (co-conspirators are considered in “privity” for *res judicata* purposes); *Discon Inc. v. Nynex Corp.*, 86 F.Supp.2d. 154, 166 (W.D.N.Y. 2000) (“Courts have held that alleged co-conspirators are ‘in privity’ with one another for *res judicata* purposes”); *McLaughlin v. Bradlee*, 599 F. Supp. 839, 847-48 (D.D.C. 1984) (defendants may “defensively assert claim preclusion against [plaintiff] even though none

of the prior suits named all six of them as defendants,” primarily because one conspiracy was alleged in the two complaints), *aff’d*, 803 F.2d 1197 (D.C. Cir. 1986); *Goel v. Heller*, 667 F. Supp. 144 (D.N.J. 1987).¹⁰

Whether privity exists such that principles of *res judicata* bar the FTC’s claim concerning coral calcium is an issue that simply cannot be decided on summary judgment. The required inquiry is extremely fact intensive and requires the trier of fact to determine identity of claims, identity of parties and whether a close or significant relationship exists. If so, the FTC’s claim may be barred entirely. If not, that conclusion may impact the reasonableness of the efforts that the DMC Defendants undertook to substantiate the claims in the infomercial, as well this court’s assessment of the nature of any remedy it might assess if any liability is determined to exist.

c. Disputed Issues Exist Regarding The Scientific Substantiation For the Opinions Expressed By Barefoot In the Infomercial

In order to demonstrate that a representation has the capacity to mislead reasonable consumers, the FTC must show that the representation is not supported by a reasonable basis. *See, e.g., Thompson Medical Co., Inc. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986). In the context of opinions regarding dietary supplements, the “reasonable basis” is generally in the form of citation to some level of scientific literature. *Whitaker v. Thompson*, 248 F. Supp.2d 1 (D.D.C. 2002) (discussing the required level of “substantiation” in connection with dietary supplement claims). In addition, the more a representation is couched as an opinion, rather than fact, the less specific substantiation is required. *Id.* Finally, if a representation is such that no

¹⁰ Another significant factor in the *res judicata* analysis is the existence of indemnification obligations running from the prior settling defendant to the later named parties. Here, it is undisputed that Barefoot agreed to indemnify the DMC Defendants in connection with any claims he made in the infomercial. As such, the later action against the DMC defendants is barred. *See, e.g. Levy v. United States*, 776 F. Supp. 831, 836 (S.D.N.Y. 1991) (“a plaintiff who has litigated a claim in a prior action may not sue a new party on the same claim in a second action if that new party could seek indemnification from a litigant in the initial action”); 18A Wright, Miller & Cooper, § 4463 (*res judicata* bars a subsequent claim against an indemnitee where the same claim has already been pursued against the indemnitor).

consumer would perceive it as other than “puffing,” no substantiation is required. *See Speakers of Sport, Inc. v. Proserve, Inc.*, 178 F.3d 862 (7th Cir. 1999) (statements that are obviously puffing are not actionable at all); *FTC v. Evans Prods. Co.*, 775 F.2d 1084, 1085 (9th Cir. 1985) (affirming district court’s determination that statements were “mere puffing”); *The Butcher Co., Inc. v. Bouthot*, 124 F.Supp.2d 750, 762 (D. Me. 2001) (“The assertion that products are ‘comparable’ in quality may well be nonactionable ‘puffery’”).¹¹ Therefore, the specific representation, and concomitant required substantiation, are factual issues that cannot be resolved on summary judgment.

Contrary to the assertions of the FTC, the DMC Defendants have amassed and submitted multiple volumes of scientific substantiation for the opinions expressed by Barefoot in the coral calcium infomercial.¹² Most of this information existed prior to the dissemination of the infomercial, and recent studies have only further confirmed the health properties and benefits of calcium, including the recent decision by the FDA to allow certain cancer claims. Nonetheless, the FTC asks this Court to reject this wealth of substantiation in favor of blind adherence to the opinions of its third-party experts. Notwithstanding that these expert opinions partially support, rather than defeat, the challenged claims, the Ninth Circuit has cautioned against reliance on expert opinions and reports without an opportunity to test those opinions and reports at trial. *FTC v. Enforma Natural Prods., Inc.*, 362 F.3d at 1217.

In the *Enforma* case, the Ninth Circuit held that there were “genuine disputes about the scientific requirements underlying Enforma’s substantiation claims.” In reaching this

¹¹ In the FTC context, puffery consists of a class of “claims that are either vague or highly subjective.” *Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1150 (9th Cir. 1984). Puffery is generally not actionable because it does not contain the kind of detailed or specific factual assertions that are necessary to prosecute a claim of false advertising. *Cook, Perkiss & Leihe, Inc. v. N. Cal. Collection Servs., Inc.*, 911 F.2d 242, 246 (9th Cir. 1990).

¹² The DMC Defendants have submitted similar materials in support of the opinions expressed in the Supreme Greens advertising, as discussed below.

conclusion, the Ninth Circuit was particularly troubled by the district court's reliance upon expert witness testimony in the face of a number of reports submitted by Enforma that appeared to undermine the expert's conclusions.¹³ In addition, as is the case here, the court noted that "[t]he FTC's own expert appears to have recognized some of the animal and in vitro tests as 'competent and reliable scientific evidence,' but evidence of a kind that could not 'substantiate' Enforma's claims." 362 F.3d at 1217.¹⁴ The Court then rejected any argument that only "double-blind placebo-controlled clinical testing" can serve to substantiate claims. Here, where the foundation of the FTC's experts' testimony is that only certain types of studies in their subjective view can substantiate certain claims, that issue "is not beyond doubt" and cannot be resolved without a trial. *Id.* Only by hearing the expert witnesses and assessing the weight to be given to their opinions, after cross-examination, can this court properly evaluate the scientific evidence in this case.

In short, while the FTC undoubtedly disagrees with the substantiation and studies submitted by the DMC Defendants, there is unquestionably a dispute over the volume and level of substantiation, and the amount required given the nature of the opinions expressed in the coral calcium infomercial. These disputes cannot be resolved before trial.

¹³ As here, in the *Enforma* case the FTC took a very aggressive view of what was required for "substantiation" that exceeded the FTC's own guidelines. The FTC maintained that only "double-blind, placebo-controlled clinical testing" could provide the required substantiation. The Ninth Circuit rejected the FTC's position, holding that the proper test was "tests, analysis, research, studies or other evidence based on the expertise of professionals in the relevant area." 362 F.3d at 1208. Noting that the FTC's own expert, as here, had recognized that the subject products did potentially have some of the benefits discussed in the advertising, the Ninth Circuit reversed the district court's sweeping rejection of the defendants' scientific evidence. *Id.* at 1217.

¹⁴ In its related complaint filed in this Court against the FTC, the DMC Defendants contend that the FTC's adoption of the "competent and reliable scientific evidence" standard violates the First and Fifth Amendments to the United States Constitution, as well as the Administrative Procedure Act. These arguments are set forth in more detail in the DMC Defendants opposition to the FTC's motion to dismiss, and are incorporated herein.

**3. Triable Issues Of Fact Exist
Concerning the Supreme Greens Infomercial**

There are significant triable issues of fact as to whether the DMC Defendants have any liability for the FTC's claims in connection with the Supreme Greens infomercial. First, as is the case with the coral calcium infomercial, the allegedly false and misleading health claims in the Supreme Greens infomercial are the expressed opinions of another defendant, Guerrero, and were not made by the DMC Defendants. Second, the DMC Defendants dispute the FTC's contention that substantiation for the claims made in the infomercial does not exist. To the contrary, the DMC Defendants have obtained and submitted with its opposition hundreds of studies, journals and related materials demonstrating that the ingredients in Supreme Greens do have the beneficial effects discussed by Guerrero. For the same reason that the Court cannot determine as a matter of law that substantiation does not exist for the opinions expressed in the coral calcium infomercial, a trial is required to assess the FTC's experts and their often inconsistent opinions and citations to determine if the advertising, based on the published literature and studies, is in fact misleading to consumers.¹⁵ When combined with the disclaimers that are associated with the infomercial and with the product labeling for Supreme Greens, the DMC Defendants' liability for the infomercial is simply not a question that can be answered without a trial.

It is well settled that in determining whether a claim is made, particularly in a lengthy visual advertisement like the advertisements at issue in this case, courts must consider the entire

¹⁵ For example, both of the FTC's experts admit that certain of the ingredients in the Supreme Greens dietary supplement do in fact have many of the properties discussed by Guerrero, and that these properties have been demonstrated to impact certain diseases. These experts nonetheless argue that there is "no" scientific support whatsoever for the claims. The problem with this testimony is that these experts, who are scientists and not consumer experts, are basing their opinions on what they perceive to be the claims communicated in the advertising. Thus, if the facts demonstrated that consumers did not perceive the advertising to make those claims, the opinions of the FTC's experts would undoubtedly be different and might actually support aspects of the advertising. Net net, the combined issues of the reality of the advertising's content, combined with the basis of both experts' testimony creates issues of fact that cannot be determined on summary judgment.

context of the advertisement, and not just the “snippets” pulled out and highlighted by the FTC. “In considering a false advertising claim, fundamental to any task of interpretation is the principal that text must yield to context.” *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001). Thus, “a court must consider the advertisement in its entirety and not ... engage in disputatious dissection. The entire mosaic should be viewed rather than each tile separately.” *Id.* Additionally, “the greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion ... the less likely it is that a finding of falsity will be supported.” *Spalding Sports Worldwide, Inc. v. Wilson Sporting Goods Co.*, 198 F.Supp.2d 59, 66 (D. Mass. 2002).

Here, it is undisputed that the “entire mosaic” of the original Supreme Greens infomercial and later versions of the show informed consumers that the infomercial was a paid advertisement, and included numerous disclaimers concerning the opinions expressed about the Supreme Greens product by Guerrero. The packaging for the product also contained the required FDA disclaimer, stating clearly that “This product is not intended to diagnose, treat, cure, or prevent any disease.” Similar disclaimers were contained in print advertising and on the Internet. According to settled law, the FTC is required to consider these disclaimers, which it fails to do, as they can render even scientifically unsupported advertisements lawful. Where it is undisputed that some substantiation does exist, the impact of the disclaimers is even greater. Because the FTC flatly rejects any of the existing substantiation for the ingredients in Supreme Greens, and further ignores the disclaimers, it has failed to demonstrate a *prima facie* element of its case on summary judgment; namely, that the infomercials are actually deceptive to consumers in light of the existing literature and disclaimers. *See Marketing Response Group*, 1996 WL 420865 at *3 (district court denied FTC’s motion for preliminary injunction as it failed to prove

that defendant's promotional materials would be construed as material misrepresentations to the average consumer.) Based on these significant issues, which cannot be determined as a matter of law without a trial, the FTC's motion for summary judgment must be denied.

a. Expressions of Opinion Are Protected by the First Amendment

Although the FTC presents its arguments concerning the Supreme Greens infomercial as unassailable, there is a significant triable issue of fact as to whether the DMC Defendants have any liability for the expressions of opinion of another defendant. As noted previously, it is firmly established that the First Amendment protects commercial speech. *Virginia State Bd. of Pharmacy*, 425 U.S. at 752. This protection is based on the principle that "such speech serves individual and societal interests in assuring informed and reliable decision making." *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978) (citations omitted). The government does not have complete power to suppress or regulate commercial speech, even if it deems such speech controversial. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n*, 447 U.S. 557, 562 (1980). Thus, administrative agencies may not simply pursue rigorous enforcement to the extent of discouraging advertising, and courts must limit the reach of federal agencies when they seek to punish protected speech without regard to the protections afforded by the First Amendment. *Standard Oil Co.*, 577 F.2d at 662.

In this case, the Supreme Greens infomercial is protected commercial speech, which invites the viewers to consider the nutritional value of Supreme Greens for the overall health of an individual. The views expressed on the infomercial are that of Guerrero, who created the supplement and maintained that he conducted clinical trials that supported the opinions he expressed in the infomercial. The infomercial was not scripted; rather, the DMC Defendants simply posed questions to Guerrero and elicited his responses. The DMC Defendants themselves made no claims about the Supreme Greens product in the infomercials, and had been assured at

all times that Guerrero had the credentials and the scientific support for the supplement that he had previously represented to the public in prior public appearances with Tony Robbins and other famous athletes and personalities.

Given the First Amendment protections on commercial speech and the fact that all of the statements in the infomercial are the opinions of Guerrero, there is a significant issue of fact that cannot be resolved on summary judgment as to the level of substantiation required by the DMC Defendants prior to the airing of the infomercial. The FTC does not contend that the DMC Defendants were provided *no* substantiation prior to airing the infomercial, only that in their view the substantiation was insufficient to meet the requirements of the FTC Act. In light of the *Garvey* case, however, that contention is far from indisputable or settled on the current record. Numerous issues of fact remain concerning whether, in light of the fact that they themselves made no statements, the DMC Defendants were “recklessly indifferent to the truth of [Guerrero’s] statements” or were “aware that fraud was highly probable and intentionally avoided the truth.” *Garvey*, 383 F.3d at 902 (citing *FTC v. Publishers Clearing House, Inc.*, 104 F.3d 1168, 1170-71 (9th Cir. 1997)). The DMC Defendants vehemently deny that this is the case, despite the FTC’s view to the contrary. In short, there is a triable issue as to whether, in light of the First Amendment concerns, the FTC has any basis for requesting the relief it seeks against the mere producer of an infomercial, who was unaware that any of the claims made about Supreme Greens may in the FTC’s view lack scientific support.

b. Disputed Issues Exist Regarding The Scientific Substantiation For the Opinions Expressed By Guerrero In the Infomercial

Contrary to the assertions of the FTC, the DMC Defendants have amassed and submitted multiple volumes of scientific substantiation for the opinions expressed by Guerrero in the Supreme Greens infomercial. In addition, before airing the show and in the course of its review

by the FTC, the DMC Defendants reviewed scientific materials, including double blind studies and articles provided by Guerrero. Much of the information submitted with this opposition existed prior to the dissemination of the infomercial, and recent studies have only further confirmed the health properties and benefits of the ingredients in Supreme Greens. Nonetheless, the FTC asks this Court to reject this wealth of substantiation in favor of blind adherence to the opinions of its third-party experts. As with the expert opinions submitted by the FTC in connection with the coral calcium advertising, however, these expert opinions partially support, rather than defeat, the challenged claims. For example, the resources discussed by Dr. Cassileth, who is primarily relied upon by the FTC to demonstrate the alleged falsity of the advertising, often directly contradict the opinions expressed. Just as one example, Dr. Cassileth states that there are no studies linking Alfalfa intake to a lower occurrence of certain diseases. However, studies cited by the DMC Defendants have stated that alfalfa “has demonstrative antineoplastic activity against a number of animal bearing carcinomas and cancer cell lines.” Similar studies exist for virtually every other ingredient in the Supreme Greens product, undermining completely Dr. Cassileth’s opinion that no such studies exist. Because it appears that the FTC’s experts selectively reviewed certain literature helpful to their opinions, while ignoring any studies that might raise doubt about these opinions, the factual disputed raised by the FTC’s own evidence entitles the DMC Defendants to test those opinions and reports at trial. *FTC v. Enforma Natural Prods., Inc.*, 362 F.3d at 1217.

**c. The FTC’s Sweeping Rejection of the
Supreme Greens Infomercial Is Unconstitutional**

In light of the significant amount of scientific literature that exists supporting the health properties of the ingredients in Supreme Greens, there is also a significant triable issue of fact as to whether the FTC can meet its prima facie case and demonstrate that the opinions expressed in

the Supreme Greens infomercial, when viewed as a mosaic and not taken out of context, were false or deceptive. This is particularly the case in light of the presence of express disclaimers throughout the infomercials informing consumers that the infomercial was a paid advertisement, and that the product was not intended to treat, cure or prevent any disease. In order to establish a violation of Section 5 of the FTC Act, the FTC must demonstrate that the representations of the DMC Defendants would mislead consumers acting reasonably under the circumstances. 15 U.S.C. §§ 45, 52; *see, e.g., FTC v. Marketing Response Group, Inc.*, 1996 WL 420865, at *3. The FTC failed to offer any evidence to show that consumers were actually misled by the claims in the Supreme Greens infomercial or that the infomercials were false and deceptive in light of the existing scientific literature and these disclaimers.

In fact, despite arguing that the infomercial is deceptive to consumers the FTC all but ignores the disclaimers throughout the infomercial, which alerted consumers to the fact that, *inter alia*, it was a paid advertisement, that the views expressed on the infomercial are solely the opinion of the guest – Guerrero, that the product does not claim to heal or cure any illness, and that individual results may vary.¹⁶ The disclaimers even informed consumers that the opinions expressed may not be supported by scientific evidence, and that no representation or warranty as to any specific result is intended. There is clearly a triable issue as to whether the FTC can meet its *prima facie* case in light of the existing science and these disclaimers, and the absence of any evidence that consumers were actually misled, and prove a Section 5 or Section 12 violation. *See Marketing Response Group*, 1996 WL 420865 at *3 (FTC failed to prove that defendant's

¹⁶ As testified to by Luke Goljan and Eileen Barrett, these disclaimers existed throughout the show and were increased over time to be of larger prominence and more frequent. In addition, many stations required additional disclaimers, including the FDA disclaimer and additional disclaimers stating that the show was a paid advertisement.

promotional materials would be construed as material misrepresentations to the average consumer.)

The FTC's outright rejection of the infomercials without considering the overall message communicated by the advertising, including disclaimers, goes against settled law that requires an analysis of disclaimers in connection with advertising that is admittedly inherently misleading. Specifically, in *Pearson v. Shalala*, 164 F.3d 650 (D.D.C. 1999) ("*Pearson I*"), a case also involving the labeling and advertising of dietary supplements and claims that such supplements could cure certain forms of cancer, the District of Columbia Circuit rejected the FDA's sweeping rejection of the challenged claims. In so doing, the Appeals Court held as a preliminary matter that the speech was protected by the First Amendment. *Id.* at 655 ("It is undisputed that the FDA's restrictions of appellants' health claims are evaluated under the commercial speech doctrine.") The Court of Appeals then recognized that disclaimers not only could render otherwise potentially misleading claims lawful, but mandated that federal agencies such as the FTC and FDA consider first whether disclaimers cure the offending speech. *Id.* at 658.

In this case, the FTC simply ignores the fact that the message in the advertising is clearly expressed as opinion, and is combined with disclaimers. Moreover, the FTC ignores the fact that these disclaimers were enhanced over time, leading the FTC staff to opine that these changes to the show reflected a "substantial improvement" and appeared to provide comfort to the DMC Defendants that the FTC had reviewed and approved the show. Only months later did the FTC take the position that no disclaimers could cure the opinions in the advertising. In *Pearson v. Thompson*, 141 F. Supp. 2d 105 (D.D.C. 2001) ("*Pearson III*"), the district court rejected similar conduct by the FDA in connection with claims by designers of dietary supplements containing folic acid. In particular, the FDA took the position that in no circumstances could disclaimers

cure the claims by the manufacturers that folic acid might prevent neural tube defects. Rejecting the FDA's argument, the court, citing *Pearson v. Shalala*, 130 F. Supp. 2d 105, 121 (D.D.C. 2001), stated:

In short, even if the FDA's criticism of the sub-claim is valid, this criticism does not make the Claim inherently misleading; rather, it suggests the need for a well-drafted disclaimer, which the FDA has steadfastly refused to even consider.

See Pearson III, 141 F. Supp. 2d at 112 (the Government "must demonstrate with empirical evidence that disclaimers similar to [those] suggested . . . would bewilder consumers and fail to correct for deceptiveness.").

Here, where the FTC has not offered one affidavit from a consumer complaining that he or she was misled by the opinions expressed in the Supreme Greens infomercials, or even considered whether the infomercials are misleading to consumers in light of the disclaimers, it has not made out its prima facie case. This action, therefore, is similar to *Whitaker v. Thompson*, 248 F. Supp.2d 1 (D.D.C. 2002). In *Whitaker*, as here, the promoters of a dietary supplement claimed that "consumption of antioxidant vitamins may reduce the risk of certain kinds of cancers." The FDA, as the FTC has done here, determined that such claims were "inherently misleading" and unsupported by competent and reliable scientific evidence, and refused to even consider the effect of disclaimers on the plaintiffs' commercial speech. The court rejected the FDA's position under the framework established in *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of New York*, 447 U.S. 557 (1980) and *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002), holding that "[t]he First Amendment does not allow the FDA to simply assert that Plaintiffs' Claim is misleading in order to 'supplant [its] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.'" *Whitaker*, 248 F. Supp. 2d at 9 (quoting *Ibanez*, 512 U.S. at 146).

As in *Whitaker*, “[i]n this case, the Government has not satisfied its burden – there is no evidence that the proposed [anti-cancer] claim, if accompanied by a disclaimer, would be deceptive or unlawful.” 248 F. Supp. 2d at 9. Numerous other cases are in accord. *See, e.g., Biogonic Safety Brands, Inc. v. Ament*, 174 F. Supp. 2d 1168, 1182 (D. Col. 2001) (holding that even if claim that pesticide is “Safe for Kids” is inherently misleading, “any misleading impression can be cured by a disclaimer”), citing *Zauderer v. Office of the Disciplinary Counsel*, 471 U.S. 626 (1985); *Symes v. Bahama Joes, Inc.*, 1988 WL 92462 (D. Mass. Aug. 12, 1988) (Zobel, J.) (“The specific disclaimers bar plaintiffs’ claims of misrepresentation”); *cf. American Home Prods. Corp. v. FTC*, 695 F.2d 681 (3d Cir. 1983) (recognizing curative effect of disclaimers on otherwise potentially misleading commercial speech).

Although DMC, ITV and Barrett have agreed to cease the allegedly misleading commercial speech and have not advertised the product at all since May 2004, there is a significant question whether the FTC can demonstrate that the infomercial is misleading and deceptive to consumers in light of the fact that the statements are expressed as opinions, there does exist a wealth of scientific support for the claims, and the existence of disclaimers.¹⁷ Thus, at a minimum, the FTC’s complete rejection of the defendant’s scientific evidence and disclaimers raises a triable issue concerning whether the FTC has established an element of its *prima facie* case.

4. There Are Disputed Issues of Fact Concerning The Liability of The Individual Defendants

¹⁷ Even if the Court were to conclude that the disclaimers did not go far enough, in light of *Pearson I* and its progeny, the Court must still assess how the existence of some disclaimers impacts the proper remedy. As noted in *Whitaker*, “[t]he case law makes it very clear that plaintiffs are harmed by the FDA’s suppression of the [cancer cure] claims because the “loss of First Amendment freedoms, for even minimal periods of time, unquestionable constitutes irreparable injury.” 248 F. Supp. 2d at 15, citing *Elrod v. Burns*, 427 U.S. 347, 373 (1976); *New York Times Co. v. United States*, 403 U.S. 713 (1971); *Lakewood v. Plain Dealer Publ’g Co.*, 486 U.S. 750, 758 (1988). Thus, even if the Court were to conclude that the prior disclaimers were insufficient, the proper remedy should be limited to requiring additional disclaimers in the future, which the DMC Defendants have already agreed to do.

Both of the individual defendants in this case dispute their individual liability in connection with either the coral calcium or the Supreme Greens advertisements. Both defendants, Donald Barrett and Robert Maihos, dispute that they themselves made any representations whatsoever. Both defendants also dispute the FTC's contention that, in light of the lack of any such representations, their reliance on the scientific evidence provided by Barefoot and Guerrero was unreasonable. *See FTC v. Garvey*, 383 F.3d at 902 (noting that even though booklet provided to individual may not have explicitly mentioned certain ingredients, "the booklet provides some relevant substantiation for the advertising claims made"). To the contrary, both Barrett and Maihos acted reasonably under the circumstances.¹⁸

Moreover, Maihos disputes that he had any role whatsoever in the creation, production or dissemination of the subject infomercials. Mr. Maihos also disputes that he had any role in or control over the scripts provided to the sales force or any other representations made in connection with either infomercial. To the contrary, Mr. Maihos' role within DMC has been and continues to be limited to an operational "back office" role, handling such issues as finance, personnel and shipping. The FTC has not provided evidence of any involvement whatsoever by Maihos in the actual production of either infomercial, control over the content of the infomercial at the time each was produced, or supervision over the editing of the infomercial prior to its dissemination publicly. In addition, the FTC has not provided any facts indicating that Mr. Maihos purchased any media for DMC or ITV, or had any control over which infomercials ran in which markets. That is, despite its comprehensive investigation, the FTC has provided no

¹⁸ For example, the FTC makes much of the fact that the defendants provided a copy of the script of the infomercial to counsel for review and counsel noted that one of the studies stated that it was conducted on pigs, rather than humans. In *Garvey*, however, the Ninth Circuit expressly recognized that the "Exercise in a Bottle" booklet relied upon by Garvey only mentioned pigs and rats, not humans. The FTC argued that this distinction between pigs and humans was determinative of Garvey's reasonableness. The court disagreed, concluding that it was reasonable for Garvey to have found that this information substantiated the claims he made. 383 F.3d at 902.

evidence that Mr. Maihos actually made *any* statement to consumers, or controlled the content or distribution of the allegedly offending statements made by others.

Instead of providing facts demonstrating that Mr. Maihos individually controlled the creation, production or distribution of the challenged infomercials, the FTC argues only that *subsequent* to the production and distribution of the Supreme Greens infomercial,¹⁹ and upon notification by the FTC that it had concerns over the infomercial, Mr. Maihos and others within ITV sought to obtain additional scientific support from Mr. Guerrero for the opinions expressed in the infomercial, and requested that the infomercial be reviewed by ITV's outside counsel. It is undisputed that ITV, with the assistance of counsel, then edited the infomercial to address the concerns raised by the FTC, including editing the tape for content and adding additional disclaimers, sent the tape to the FTC for its review, and distributed the edited tape to media outlets.²⁰ However, the FTC provides no facts that Mr. Maihos had any involvement in the actual editing or distribution of the advertising at any time.

In *United States v. Building Inspector of America, Inc.*, 894 F. Supp. 507 (D. Mass. 1995), for example, an individual officer in a similar position to Mr. Maihos challenged the FTC's evidence that he was sufficiently in control of the offending statements to warrant individual liability. Although, as here, the FTC provided some evidence that the defendant "had some knowledge of at least some of the misrepresentations," Judge Gertner, denying summary judgment, rejected the FTC's contention that this evidence established that he "participated directly in the practices or acts, or had the authority to control them." *Id.*, at 520, quoting *FTC v.*

¹⁹ The FTC has advanced no facts connecting Mr. Maihos to the Coral Calcium infomercial. Rather, the FTC's limited allegations and argument as to Mr. Maihos relate solely to his alleged review of the Supreme Greens infomercial after it was produced and the FTC raised its initial concerns over some of the infomercial's content.

²⁰ Notably, the FTC argues that Mr. Maihos communicated with Mr. Guerrero and counsel regarding the infomercial, but does not provide any facts indicating that subsequent to those conversations he controlled the purchase of media for the infomercial or its distribution to media outlets.

Amy Travel Service, Inc., 875 F.2d 564, 573 (7th Cir. 1989).²¹ Likewise, although the defendant was involved in reviewing and editing certain statements, there was no evidence provided by the FTC demonstrating whether that defendant “had actual authority in the company to determine the final content” of the statements that were distributed. *Building Inspector of Amer.*, 894 F. Supp. At 520. Finally, Judge Gertner described as “sketchy at best” the FTC’s evidence that the defendant had any direct involvement in making the misleading statements.

Similarly here, the FTC has provided no evidence beyond the fact that Mr. Maihos was an officer of DMC and ITV involved in some aspects of the companies’ business. The FTC has provided no evidence that Mr. Maihos was involved in making any of the misleading statements, the production of those statements, or their distribution. The FTC has also failed to demonstrate that Mr. Maihos had the requisite control over these statements or their distribution to warrant the imposition of individual liability for the statements.

B. THE FTC HAS NOT MET ITS BURDEN OF DEMONSTRATING SALES PRACTICE VIOLATIONS

The FTC has never disputed that DMC provides all of its customers a money-back guarantee and allows them to cancel any purchase program they may have signed up for at any time. The FTC has also never disputed the evidence submitted by the DMC Defendants stating that in light of these policies, it would run counter to business logic to have policies that encourage sales representatives to place customers on a sales program for which they have not agreed, only to have that customer immediately cancel. Instead, the FTC submits highly suspect,

²¹ In addition to the issue of control, the Court in *Building Inspector of America* noted that the FTC must also show that the defendant had either “actual knowledge” of material misrepresentations, reckless indifference to the truth or falsity of the misrepresentations, or an awareness of a “high probability” of fraud. 894 F. Supp. at 518 (citing cases). Here, the facts submitted by the FTC, which show that Mr. Maihos sought additional support for the statements in the Supreme Greens infomercial from Mr. Guerrero, had the infomercial reviewed by counsel, and provided an edited copy to the FTC for review, all belie the contention that he had any actual awareness of misrepresentations or fraud. To the contrary, these facts demonstrate that Mr. Maihos sought to comply in all respects with the law.

and very debatable, “evidence” in an effort to demonstrate that customers are routinely placed on certain purchase programs without their consent. Unfortunately for the FTC, this evidence, in the form of undercover calls and declarations by FTC staff members, defeats rather than supports the FTC’s arguments. Clearly the evidence does not overcome the FTC’s burden to show there are no issues of fact concerning these matters.

In support of its claims of widespread sales practice violations, the FTC has placed before the Court the declaration of Stefano Sciolli, a database technician with the FTC. Mr. Sciolli has never previously been identified as a witness in this case, either as an expert or otherwise. Nonetheless, in his declaration, Mr. Sciolli claims that he has reviewed the DMC database to determine the number of customers that complained during the relevant period about allegedly being placed on autoship or continuity plans without their consent. This analysis by Mr. Sciolli shows that *fewer than 1%* of DMC’s customers raised such complaints over a several year period. As testified to by DMC’s head of customer service, Catherine Ratcliffe, as well as by Shauna Favolora, who handles the company’s relationships with its merchant accounts, DMC’s rate of customer complaints for alleged unauthorized charges is exceptionally low for the telemarketing industry, in which such complaints can average 10% or more of all customers. In addition, DMC has always maintained oversight of the sales floor, and has increased that oversight since 2003. Although 1% is a remarkably low rate, DMC continues to make efforts to lower the rate even further.

In addition to Mr. Sciolli’s declaration, the FTC also relies upon certain select transcripts of undercover calls made by an agent of the FTC, Christina Turner, and implies that these transcripts are representative of the overall calls that were made to the call center.²² As with its

²² The FTC originally submitted three transcripts to the Court in connection with its renewed motion for a receiver. After pressing for any and all other transcripts or recordings that might exist, the FTC initially stated that there were

motion to amend the preliminary injunction, which was recently denied by the Court, the FTC selected certain transcripts to submit to the Court, but provided the Court with no information about how many total calls were made by Ms. Turner, what the substance of those calls contained, or whether those calls demonstrated that the practices alleged were in fact widespread. As the FTC well knows, DMC's sales staff handles thousands of calls per day. Thus, the context of the FTC's select sampling of a few calls is critical, and the lack of that context renders the FTC's undercover call "evidence" meaningless, and certainly cannot overcome the FTC's burden of demonstrating that there are no disputed issues of fact concerning the existence of these practices. Nonetheless, the FTC has provided no information to determine the context of these calls, despite its burden of demonstrating that context.

Given the importance of the context of the FTC's evidence of its calls to DMC's sales personnel, the FTC's failure to provide that context alone requires denial of the motion. Specifically, upon finally receiving copies of certain undercover transcripts, it became clear that these transcripts, rather than demonstrating a pattern of efforts to place consumers on the autoshop program without their consent, showed that the majority of DMC sales staff conduct themselves exactly as they should, by making certain the customer understands the terms of DMC's various programs and by obtaining their consent to the program before placing the order or charging the customer.²³ For example, in one transcript provide by the FTC in discovery, the

four additional transcripts. After more time passed, the FTC admitted that four additional recordings existed, but they had not been transcribed. After these calls were quickly transcribed, they were produced. How many additional recordings of calls exist, or how many total calls were made from 2003 through the present remains unknown. In addition, the FTC still has not produced the tapes of any of the undercover calls made by Ms. Turner or anyone else, preventing the DMC Defendants from truly understanding the context of these calls, the tone of the calls and whether the investigator induced the alleged violative conduct from the sales representative.

²³ As noted in the DMC Defendants' previously filed motion for a continuance and sanctions, the FTC would agree to produce these transcripts only if the DMC Defendants would agree to restrict them to "attorneys' eyes only" and would not file them with the Court unless filed under seal. Given the Court's local rules regarding filings under seal, the transcripts have not been filed with this opposition. However, the DMC Defendants will file the transcripts in whatever form the Court deems appropriate if it wishes to review them.

sales representative spent extra time with the undercover agent to explain the program, repeatedly stating that she wanted the customer to be comfortable with her order and understand the different plans. Contrary to the FTC's arguments, the sales representative then stated that she was *not* placing the customer on autoship, and so the customer did not need to worry about subsequent charges. Finally, the sales representative explained that the customer could return the product for a full refund for ninety days, as per company policy with every customer. This one example of a sales representative acting entirely appropriately defeats the FTC's motion.

These transcripts, combined with the data reviewed by Mr. Sciolli and the affidavits of Ms. Ratcliffe and Mr. Callahan, demonstrate that there are numerous issues of fact concerning the FTC's claims of sales practice violations, both historically and presently. Moreover, the FTC still has not provided this Court or the DMC Defendants with any representation regarding the total number of undercover calls made to the DMC call center from 2003 to the present, despite repeated requests and written discovery seeking this information. Without this basic information, the FTC's "evidence" is not evidence at all and must be rejected by the Court. On that basis alone, the FTC's motion for summary judgment should be denied.

C. EVEN IF LIABILITY EXISTED, THERE ARE ISSUES OF FACT THAT PRECLUDE AN ASSESSMENT OF THE APPROPRIATE REMEDY

The FTC may not use Section 13(b) of the FTC Act, 15 U.S.C. § 53(b) (2003), to remedy past violations of the law. Instead, the FTC may only seek an injunction "when it believes that a person 'is violating, or is about to violate' any law enforced by the FTC," or when such prior violations are likely to reoccur. *Evans Products Co.*, 775 F.2d at 1087-88 (internal citation omitted). When determining whether the FTC's request for injunctive relief is appropriate, courts also must consider the voluntary cessation by a defendant of challenged practices, and its efforts to conform to the applicable laws. *U.S. v. Toys "R" Us, Inc.*, 754 F.Supp. 1050, 1058-59

(D.N.J. 1991). See *SEC v. The American Bd. of Trade*, 751 F.2d 529, 537 (2d Cir. 1984) (court must assess voluntary cessation of activities in analysis of likelihood of future violations and appropriateness of permanent injunction); *SEC v. Bausch & Lomb, Inc.*, 565 F.2d 8, 18 (2d Cir. 1977) (“it is well settled that the Commission cannot obtain relief without positive proof of a reasonable likelihood that the past wrongdoing will recur”); *CFTC v. Commodities Fluctuation Sys., Inc.*, 583 F. Supp. 1382, 1385-86 (S.D.N.Y. 1984) (refusing to grant injunction after reviewing “the totality of the circumstances surrounding the particular defendant and the violations committed”).

Recognizing the prospective nature of the remedies it seeks, the FTC has placed before the Court evidence concerning the DMC Defendants’ current advertising, which also formed the basis for its motion to amend the existing preliminary injunction for the appointment of a receiver.²⁴ Without revisiting all of the arguments in opposition to the FTC’s claims regarding this current advertising, which are set forth in the DMC Defendants’ opposition brief and supplemental brief in response to that motion, needless to say there are many disputed issues of fact regarding the FTC’s claims of continuing violations of law.²⁵ To the contrary, the DMC Defendants have undertaken extraordinary efforts to enhance their compliance, including hiring additional in-house legal and scientific advisory staff, additional sales managers and compliance personnel, and additional customer service representatives. These efforts must be evaluated and considered by the Court in determining the appropriate remedy, if any, in connection with the claims asserted by the FTC.

²⁴ On January 19, 2006, the Court denied the FTC’s motion, while noting that one of the DMC Defendants current advertisements appeared to be in violation of the existing preliminary injunction. Upon receiving the Court’s order, the DMC Defendants immediately modified the subject advertising and the product to assure that no continuing violations of the Court’s orders were occurring.

²⁵ The DMC Defendants opposition to the FTC’s motion to amend the preliminary injunction, and its supplemental opposition brief are incorporated herein by reference.

The Court must also evaluate the propriety of the FTC's request for a \$54 million restitution order. Such an order, which bears no relation whatsoever with the profits actually received by the DMC Defendants, would undoubtedly put DMC and its 350 employees out of business.²⁶ As such, such a judgment would effectively accomplish what the FTC has otherwise sought to achieve through the appointment of a receiver, shutting down DMC and prohibiting future speech. Any injunctive relief ordered by a Court must have a "reasonable relation to the unlawful practices found to exist." *Standard Oil Co.*, 577 F.2d at 662 (citing *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-5 (1965)). Thus, "the Court should not grant relief beyond what is needed."²⁷ *FTC v. Crescent Pub. Group, Inc.*, 129 F. Supp. 2d 311, 326 (S.D.N.Y. 2001). Where constitutional freedom of speech considerations are involved, less restrictive measures must be considered. "First Amendment considerations dictate that the Commission exercise restraint in formulating remedial orders which may amount to a prior restraint on protected commercial speech." *Standard Oil Co.*, 577 F.2d at 662.

Apparently appreciating that an excessive restitution order will effectively shut down the business of an advertiser, several courts, and the FTC itself, has exercised discretion in fashioning remedial orders. In *In re Pletschke*, 2002 WL 275697 (F.T.C. Feb 22, 2002), for example, the FTC fashioned an order that provided for notification to consumers of the FTC

²⁶ As Donald Barrett states in his Supplemental Affidavit, while the company has been experiencing growth since 2003 and has increased its overall value since that time, the company's net worth is well below \$54 million, which means that a judgment for that amount would effectively put the company out of business. See Supplemental Affidavit of Donald Barrett, dated January 26, 2006.

²⁷ The FTC concedes that Section 13(b) of the FTC Act does not specifically provide for monetary relief. Nonetheless, certain courts have concluded that a Court issuing injunctive relief may evaluate the appropriateness of other remedies under its general equity powers. Equity, however, cuts both ways. Contrary to the arguments advanced by the FTC, equity does not require the Court to issue any specific monetary award. Rather, equity allows the Court to fashion a remedy, if required at all, tailored to the facts and circumstances of the case before it, including whether the relief will effectively shut down a company and put 350 Massachusetts employees out of work. See *Hannahs v. New York State Retirement Sys.*, 656 F. Supp. 387, 392 (S.D.N.Y. 1987) (equity properly considers effects of its decree and the underlying circumstances on third parties, whether represented in the litigation or not).

action and an opportunity for those customers to obtain a refund if they desired. In this way, consumers that believed they had been harmed could obtain a refund, without causing the permanent termination of the business. See also *In re Valuevision Int'l, Inc.*, 2001 WL 968398 (F.T.C. Aug. 22, 2001) (notification and opportunity for refund in connection with weight loss product); *In re Formor, Inc.*, 2001 WL 874513 (F.T.C. Jul. 30, 2001) (notification and opportunity for refund in connection with dietary supplement); *In re Forrest*, 2001 WL 877326 (F.T.C. July 30, 2001) (same); *In re Panda Herbal Int'l, Inc.*, 2001 WL 877328 (F.T.C. July 30, 2001) (same); *In re CMO Dist. Centers of America*, 2000 WL 678575 (F.T.C. May 16, 2000) (same). Similarly, in *FTC v. Gem Merchandising Corporation*, 87 F.3d 466, 467 (11th Cir. 1996), the district court rejected the FTC's request for a \$10 million blanket restitution order, instead fashioning an alternative remedial order tailored to the facts of that case.²⁸ Regardless of what the ultimate remedy, if any, might be, the record demonstrates that a determination of that remedy cannot be made prior to a trial. As in *FTC v. P.M.C.S., Inc.*, the DMC Defendants "dispute the proportion of consumer redress they are liable for, if any." 21 F.Supp.2d at 192. In addition, the DMC Defendants dispute the FTC's contention that the products sold "were a total fraud and essentially worthless." *Id.* For these reasons, material fact permeate this dispute, precluding summary judgment in favor of the FTC.

²⁸ The FTC's request for a \$54 million restitution order for the purported benefit of consumers also seems a bit disingenuous in light of its prior settlements with Barefoot, Trudeau, Guerrero, Geremesz and Howell. For example, Trudeau's sales of coral calcium exceeded \$120 million. Nonetheless, the FTC settled with Trudeau for \$2 million and allowed him to remain in business. Barefoot settled for no payment, Guerrero for \$25,000, Geremesz for \$10,000 and Howell for \$5,000. The DMC Defendants have repeatedly requested that the FTC provide a settlement figure in an effort to resolve this case and move forward. The FTC has refused to do so.

III. CONCLUSION

Based on the foregoing reason, the FTC's Motion for Summary Judgment should be denied, and this matter should proceed to trial.

DIRECT MARKETING CONCEPTS, INC., ITV
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Dated: January 27, 2005